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Filed : November 30, 2001

### REMARKS

Claims 11, 12 and 15 have been amended by this paper and previously withdrawn Claims 1-10, 28, 29 and 36-57 have been canceled. Claim 13 was previously canceled, and new Claims 58-60 have been added. Hence, by this paper, Claims 11, 12, 14-27, 30-35 and 58-60 are presented for examination.

The specific changes to the amended claims are shown in the above section entitled IN THE CLAIMS. On this set of pages, the insertions are underlined while the ~~deletions are stricken through~~.

In the Office Action mailed January 11, 2005, Claims 11, 12, 14-27 and 30-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kellogg et al. (U.S. Patent No. 6,063,589).

Among other things, the Examiner states that “Kellogg discloses an optical bio-disc that comprises a substrate (col. 8, lines 6-38) having encoded information being readable by a disc drive assembly to control rotation of the disc (col. 8, line 37 – col. 9, line 20).” Applicant disagrees that such a feature is taught or suggested by this reference, particularly with regard to encoded information directed to control rotation of the disc. The Examiner particularly points to col. 8, lines 41-44, which were quoted in Applicant’s prior response. There, Applicant noted that this referenced language is directed to “means for encoding instrument control programming ...”. Applicant has been unable to identify any further information clarifying what “instrument” would be, and thus what “instrument control programming” would entail.

In the instant Office Action, the Examiner states that the word “instrument” is defined by Webster’s Ninth New Collegiate Dictionary as “a measuring device for determining the present value of a quantity under observation.” In response, Applicant recognizes that Webster’s Ninth New Collegiate Dictionary indicates that the term “instrument” refers to a “measuring device...”. Thus, “instrument control programming” as described in the Kellogg reference would reasonably be interpreted to mean programming for control of such a measuring device.

In the Office Action, the Examiner also states that “it is inherent that there is a means to read the encoded information on the substrate because Kellogg discusses the disc can be compact discs, and it is known in the art that compact discs are read by a disc drive assembly.” Thus, the Examiner has noted that the encoded information being read from Kellogg could be read by a

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disc drive assembly. However, Applicant's claim is directed to "encoded information being located on the bio-disc and configured so as to be readable by a disc drive assembly to control rotation of the disc" (emphasis added, *see, e.g.*, Claims 11 and 12, Claim 15 includes a similar limitation). Applicant submits that encoded information read by a disc drive to control "a measuring device" (applying the logic set forth in the Office Action) is neither the same, nor does it suggest encoded information located on the bio-disc and configured to be read by the disc drive assembly to control rotation of the disc. There is simply neither any teaching nor suggestion of such a feature. Nor is there any teaching or suggestion of a bio-disc having the claimed configuration wherein "rotating the substrate in response to the encoded information delivers a metered amount of the liquid component to the assay zone" (emphasis added, *see, e.g.* Claim 11, Claims 12 and 15 have similar limitations).

In this Office Action, the Examiner has again indicated that Kellogg discloses "an assay zone in fluid communication with the metering chamber so that when a sample is deposited in the antechamber and a rotation is applied, a metered amount of liquid component is moved to the assay zone (col. 17, lines 5-21, emphasis added). In response, Applicant again notes that there is no discussion as to the metering of the flow, or of the control of amounts of fluid to be moved. The reference is, instead, directed to the idea that fluid movement is controlled by capillary pressure, produces "valves" which require the application of a particular pressure on the fluid to induce fluid flow.

In the Office Action, the Examiner refers to Figures 6A-K of Kellogg as teaching "a separation chamber in fluid communication with the antechamber (302; metering capillary allow extra sample to overflow, which separates the sample volume)." The specification describes the entry capillaries 302 at col. 14, line 63 – col. 15, line 6, noting that "the length of this metering capillary array was sufficient to contain a total volume of about 20  $\mu$ l." However, there is no teaching as to how any metering is performed in the chamber 302. In fact, stepping through Figures 6A-K, it becomes readily apparent that the entire amount of fluid contained in the entry port 301 is transferred through the entry capillaries 302 to a fluid chamber 303. Contrary to the Examiner's statement regarding capillaries 302, there is no ability to allow extra sample to overflow from the entry port 301 or entry capillaries 302. Thus, Applicant submits that metering is not taught. Furthermore, since all of the material is transmitted from the entry port 301

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through the entry capillaries 302, there is no separation of any sample volume provided for in either of those components.

In the Office Action, the Examiner also states that the Kellogg reference teaches a “metering chamber in fluid communication with the separation tube (303; fluid chamber is connect to the metering chamber and also is provided with a overflow line 304 for metering).” Applicant is unclear as to why the fluid chamber 303 would also comprise a metering chamber if the entry capillaries 302 were metering chambers. In fact, Applicant submits that there is no teaching or suggestion in Kellogg of a metering chamber in fluid communication with the fluid outlet of a separation chamber “so as to receive the liquid component of the suspension transmitted through the fluid outlet port” (*see, e.g.*, Claims 11, 12 and 15). No such metering of a liquid component received from a separation chamber is either taught or suggested by Kellogg, which is a device having an entirely different configuration.

Applicant notes that chamber 303 does include an overflow line 304, but there is no teaching that this configuration is used as a “separation chamber.” In fact, the first fluid chamber 303 is connected to a second fluid chamber 307 via a channel 305. Applicant notes that channel 305 “is positioned at the most radially distal point of the first fluid chamber” (col. 15, lines 34-35). There was no separation of components of a particulate suspension in the entry port 301, nor in the capillaries 302. Likewise, there is no such separation of such components taught with respect to chamber 303. Rather, all of the fluid of chamber 303, other than excess fluid which was transmitted out of chamber 303 via channel 304, is communicated through channel 305 to chamber 307.

In contrast, the optical bio-disc of the present application includes a

“separation chamber in fluid communication with the antechamber and configured such that a first portion of the separation chamber is closer to the antechamber than a second portion of the separation chamber.”

No such configuration is taught in Kellogg. Further, Applicant’s claims include

“a fluid outlet port located between the first and second portions of the separation chamber at a position selected to permit outward transmission therethrough of a liquid component of a particulate suspension when the suspension is contained in the separation chamber and when the substrate is rotated in response to the encoded information, while substantially preventing outward transmission therethrough of a particulate matter component of the suspension.”

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(Emphasis added, *see, e.g.*, Claim 11, similar limitations are included in Claims 12 and 15).

Applicant submits that the fluid outlet configuration as defined by Applicants' claims is exactly opposite to the structure of the Kellogg device illustrated at Figures 6A-K. Further, the Kellogg reference does not disclose a configuration as defined by Applicant's claims, wherein an antechamber is in fluid communication with a separation chamber constructed as defined in Applicant's claims, which is connected to transmit a liquid component of a particulate suspension to a metering chamber, from whence a metered amount of the liquid component is communicated to an assay zone. Such a bio-disc configuration is neither taught nor suggested by the Kellogg reference, let alone such a configuration which includes the additional limitations set forth in at least Applicant's independent Claims 11, 12 and 15. Accordingly, Applicant respectfully submits that independent Claims 11, 12 and 15 each define subject matter that is patentable over the Kellogg reference.

In view of the above, Applicant respectfully submits that independent Claims 11, 12 and 15, as presented herein, define subject matter that is patentable over the art of record. Furthermore, since Claims 14, 16-27, 30-35 and 58-60 each depend from one of independent Claims 11, 12 and 15, these dependent claims also define subject matter that is patentable over the art of record for at least the reasons set forth above with respect to the independent claims. Accordingly, Applicant respectfully submits that Claims 11, 12, 14-27, 30-35 and 58-60 are now in condition for immediate allowance and such prompt allowance of the same is respectfully requested.

#### CONCLUSION

The Applicant has endeavored to address all of the concerns of the Examiner in view of the recent Office Action directed to the above-identified application. Accordingly, amendments to the claims, the reasons therefor and arguments in support of the patentability of the pending claims are presented above.

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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